US008961526B2

(12) **United States Patent**
Burroughs

(10) **Patent No.: US 8,961,526 B2**
(45) **Date of Patent: Feb. 24, 2015**

(54) **SYSTEM AND METHOD FOR ORIENTING ORTHOPEDIC IMPLANTS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 487 days.

(21) Appl. No.: **13/303,728**

(22) Filed: **Nov. 23, 2011**

(65) **Prior Publication Data**

US 2012/0143268 A1 Jun. 7, 2012

Related U.S. Application Data

(60) Provisional application No. 61/458,396, filed on Nov. 23, 2010.

(51) **Int. Cl.**

A61B 17/56	(2006.01)
A61B 19/00	(2006.01)
A61F 2/46	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 19/5244*** (2013.01); *A61B 19/56* (2013.01); *A61B 2019/5248* (2013.01); *A61B 2019/5272* (2013.01); *A61F 2/4609* (2013.01); *A61F 2002/4687* (2013.01)

USPC ..... **606/86 R**

(58) **Field of Classification Search**

USPC ..... 600/407, 424, 587; 606/86 R, 91, 130

See application file for complete search history.

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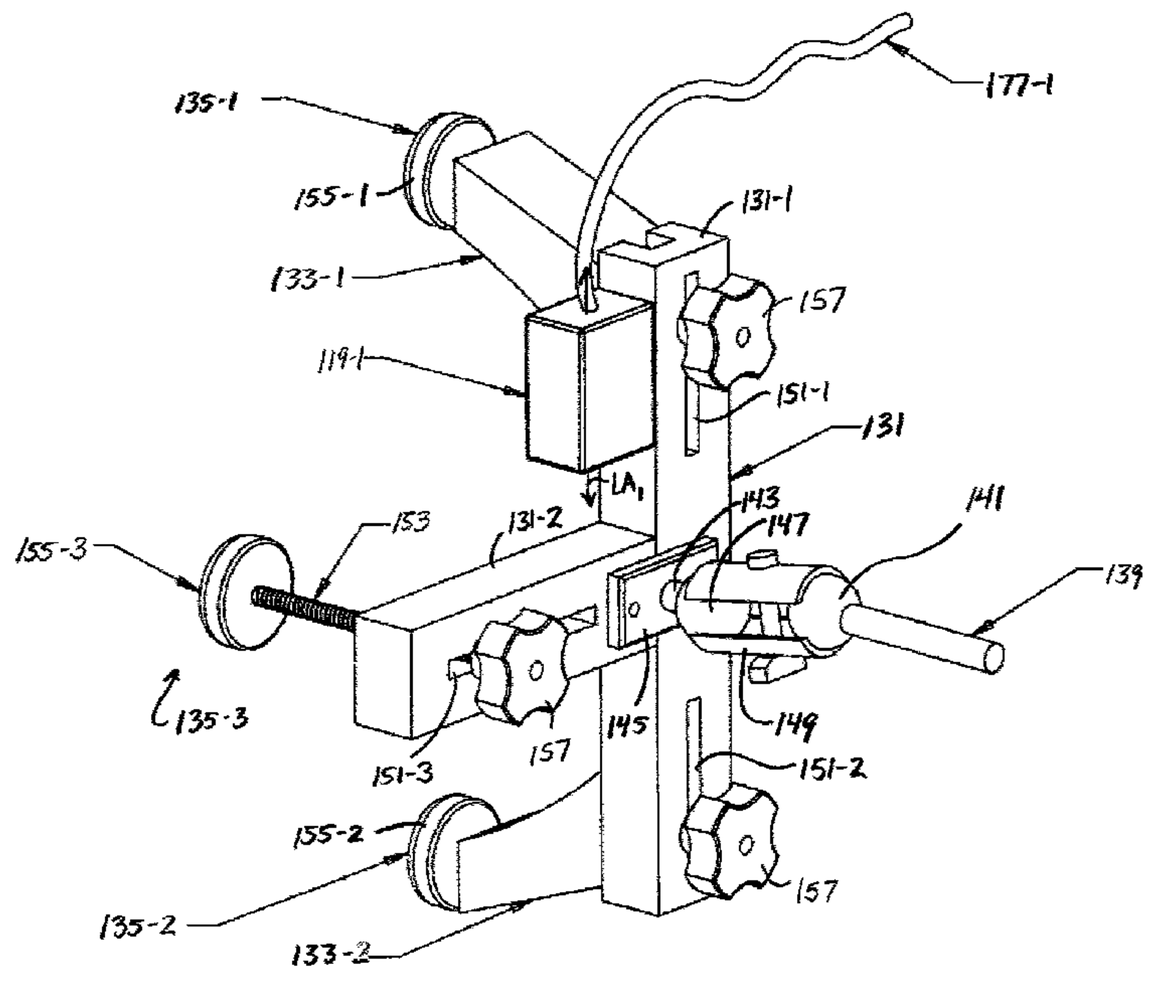
(57) **ABSTRACT**

A surgical guidance system for properly orienting a surgical instrument, such as an acetabular cup inserter, within a patient relative to a plurality of anatomical reference points includes a support device for retaining the patient, a reference sensor fixedly coupled to the support device and a tool sensor removably coupled to the instrument. The support device includes a plurality of abutment pads that directly contact the plurality of anatomical reference points. A processor is electrically connected to the reference and tool sensors and is programmed to collect spatial orientation data compiled from each sensor. Using the spatial orientation data, the processor determines in real-time the actual orientation of the surgical instrument relative to the anatomical reference points. An indicator is electrically connected to the processor and provides a feedback signal that assists the surgeon in properly orienting the instrument relative to a user-defined acceptable range.

18 Claims, 5 Drawing Sheets



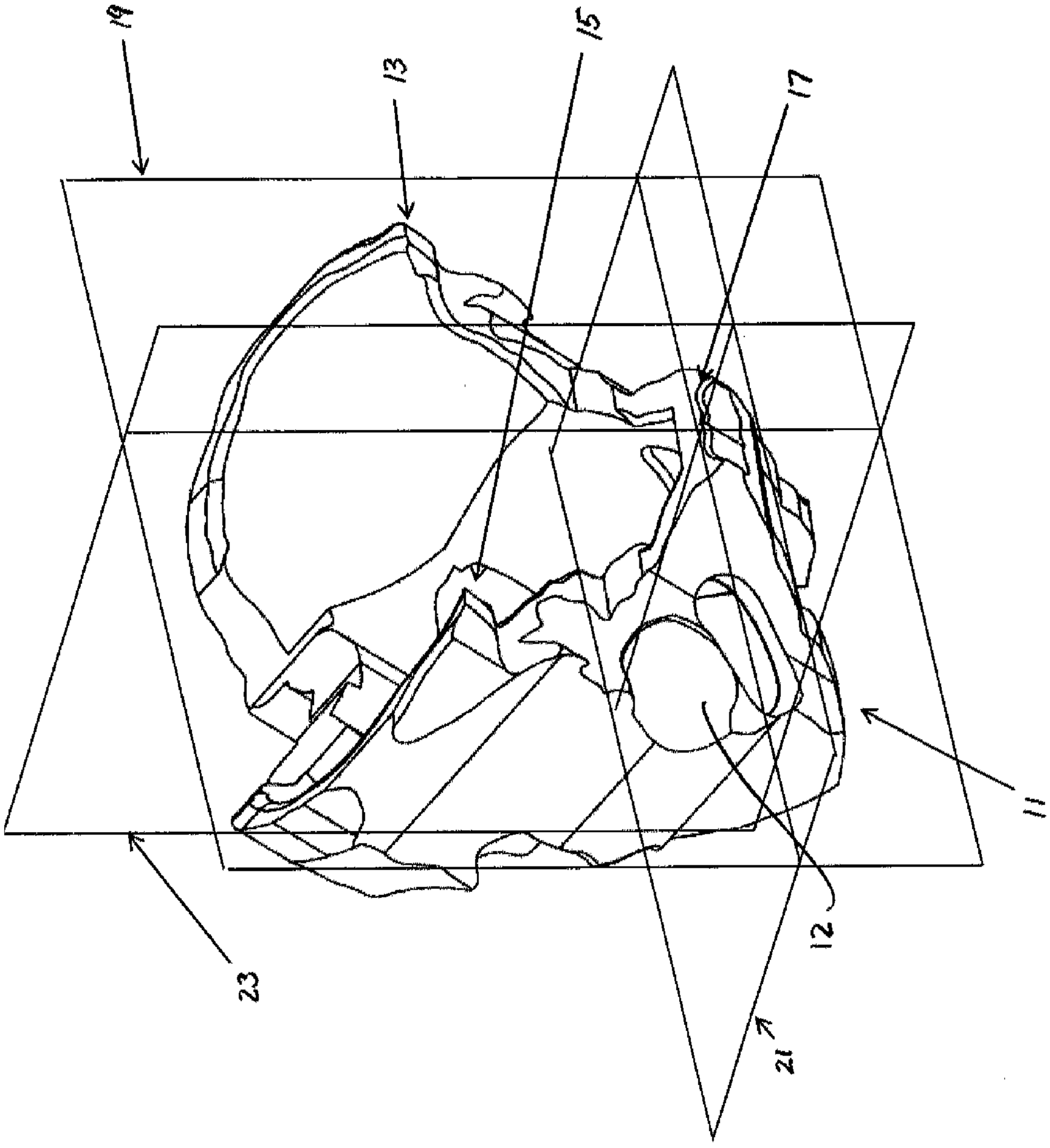


FIG. 1

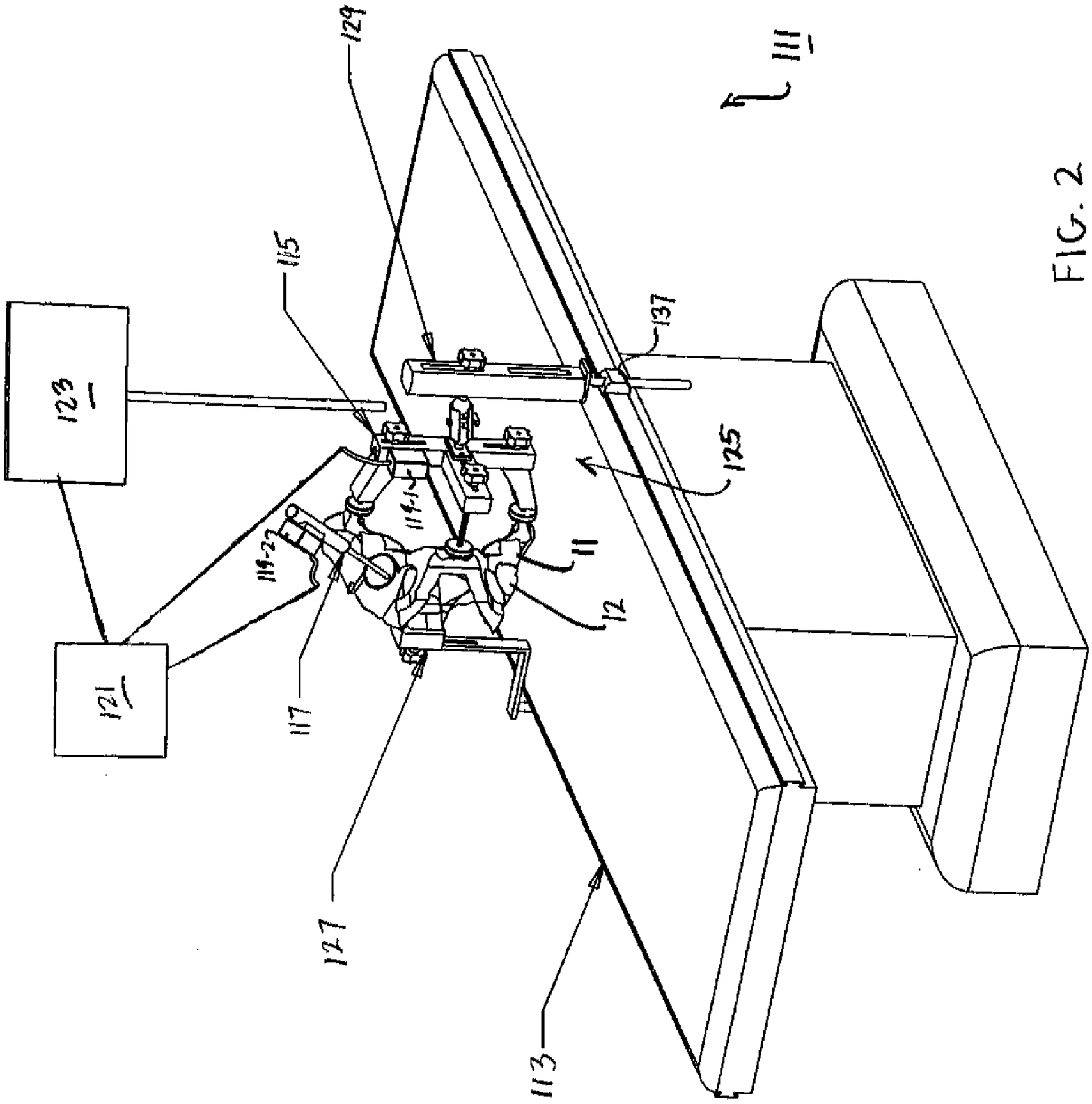
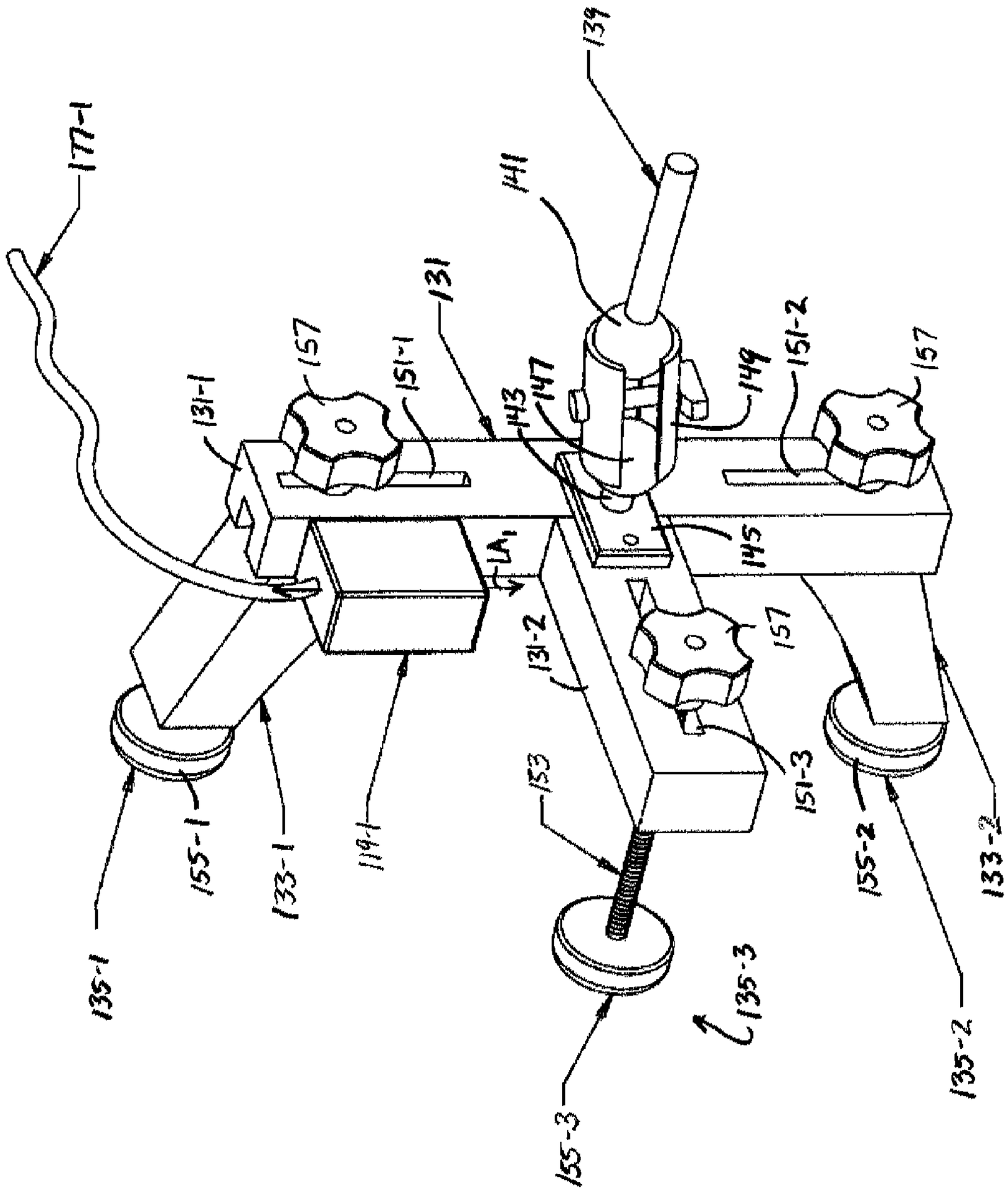


FIG. 2


177-1
135-1
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143
147
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FIG. 3

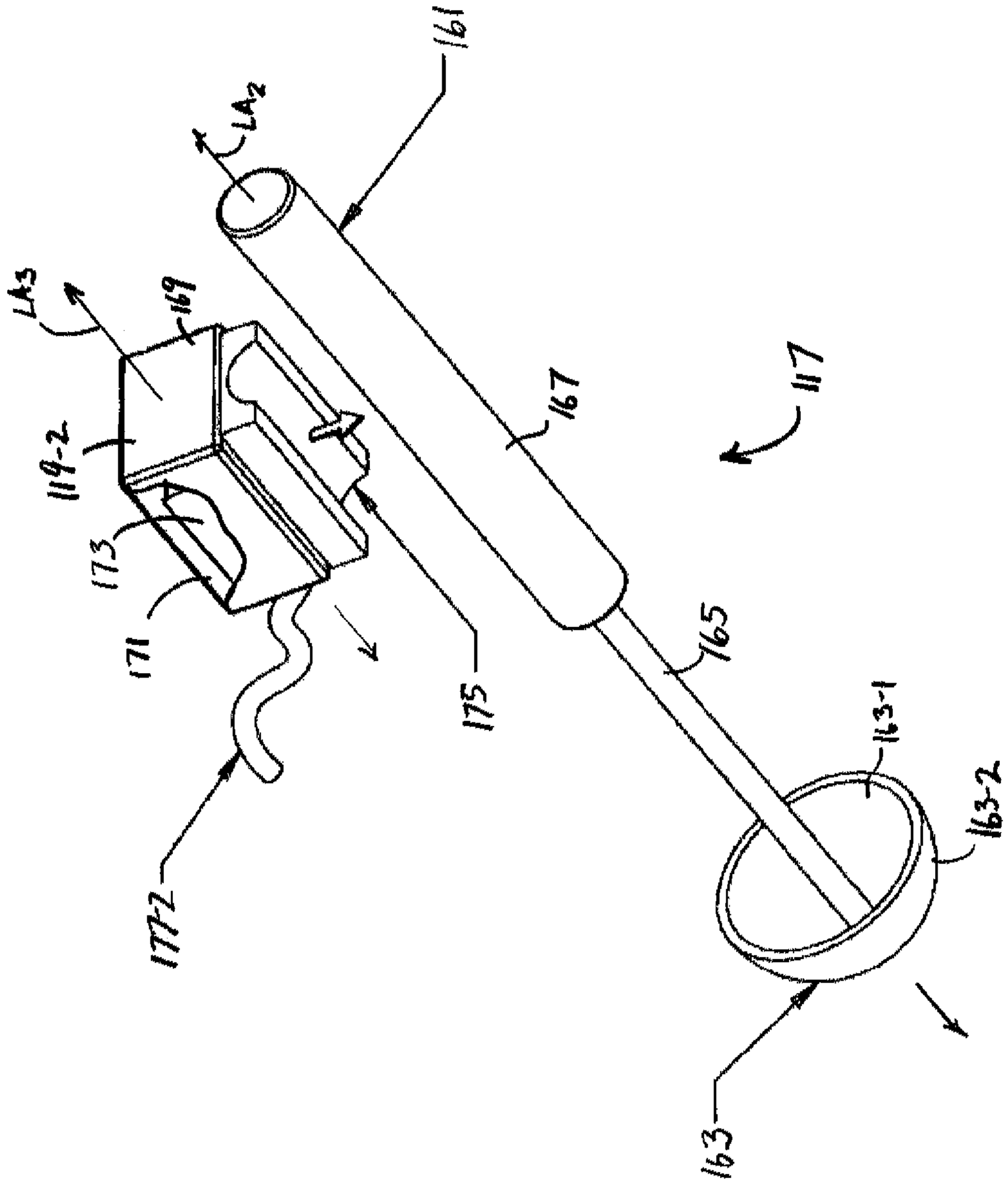
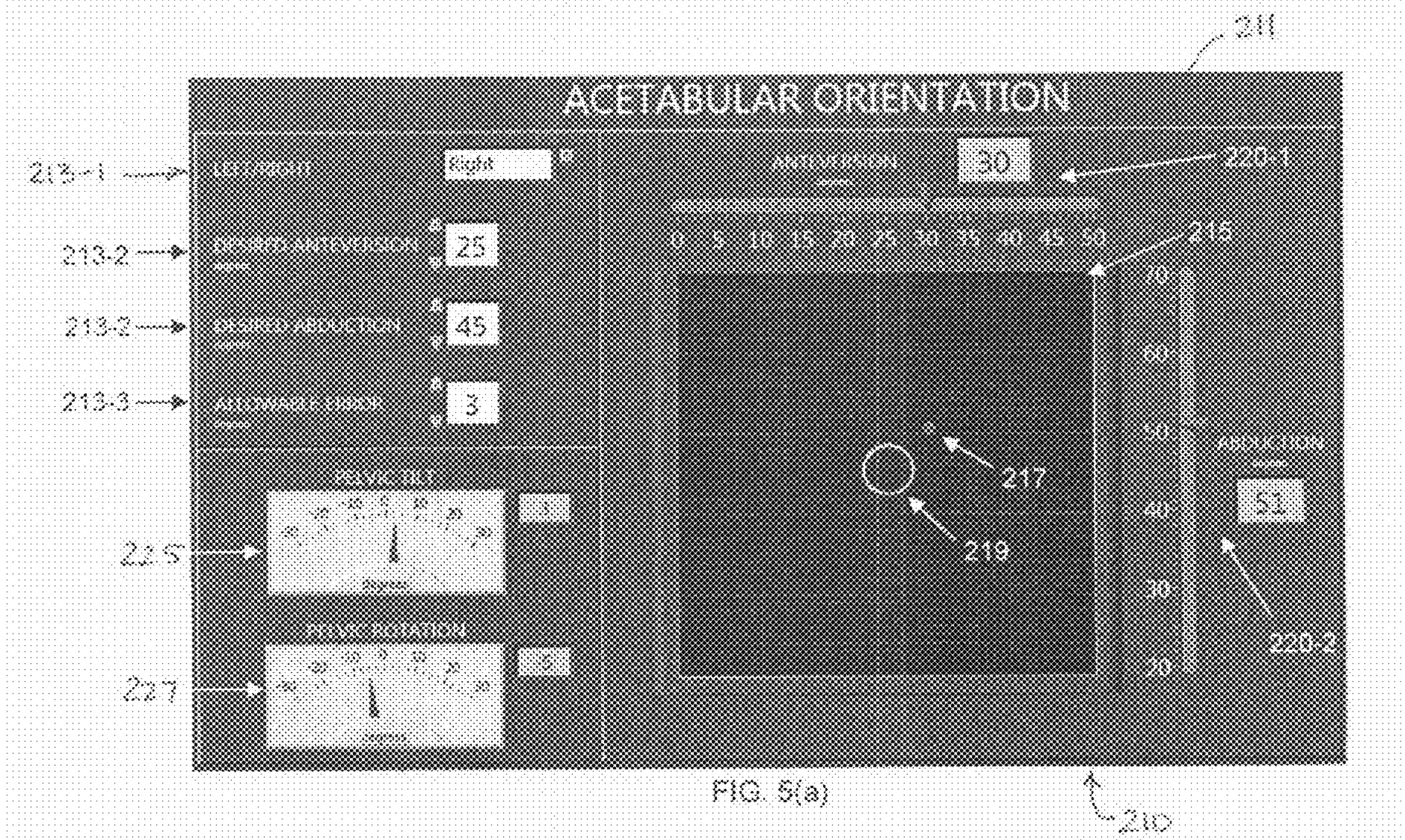


FIG. 4


211
ACETABULAR ORIENTATION
213-1
213-2
213-3
215
217
219
220-1
220-2
223
225
227
Right
25
45
3
ANTEVERSION
INCLINATION
51
FIG. 5(a)
210

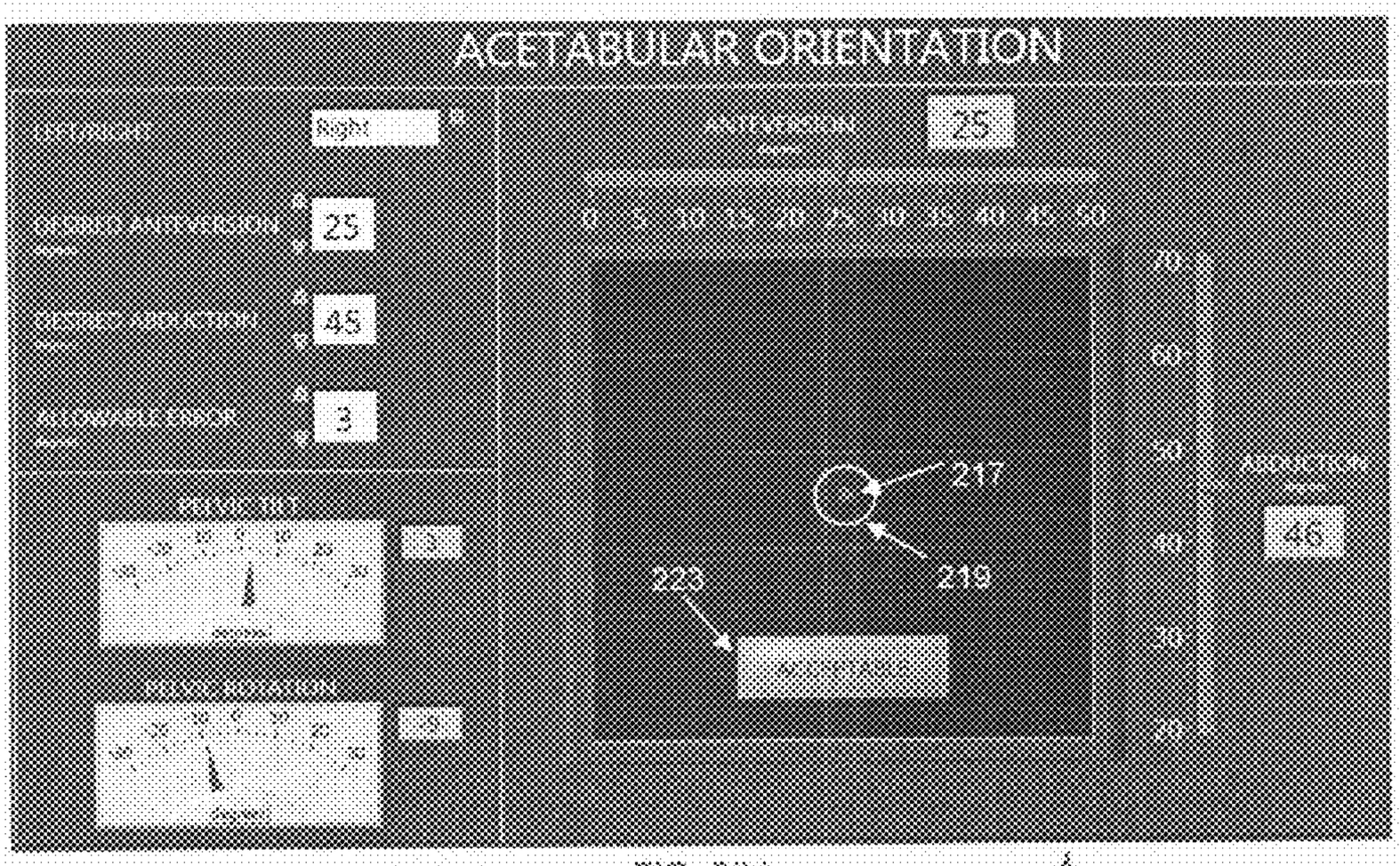

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FIG. 5(b)
221

SYSTEM AND METHOD FOR ORIENTING ORTHOPEDIC IMPLANTS

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/458,396, which was filed on Nov. 23, 2010 in the name of Brian R. Burroughs, the disclosure of which is incorporated herein by reference.

FIELD OF INVENTION

The present invention relates generally to systems and methods for surgically implanting prosthetic components and more particularly to surgical guidance systems for use in properly orienting orthopedic implants in a patient.

BACKGROUND OF THE INVENTION

The acetabulofemoral joint, commonly referred to simply as the hip joint, is a ball-and-socket joint that is formed through articulation of the rounded, ball-shaped head of the femur (commonly referred to in the art as the femoral head) within the cup-like hip socket, or acetabulum, that is formed in the pelvic bone. Functional limitations and discomfort in the hip joint can result from a myriad of different factors, such as arthritic conditions, degeneration of the femoral and pelvic bones and/or physical trauma. In extreme circumstances, regression of the hip joint ultimately necessitates the implantation of prosthetic components to restore useful functionality of the hip joint.

For instance, total hip replacement surgery is an increasingly common surgical procedure that involves replacement of the femoral head and the acetabulum with corresponding implantable prosthetic components. In the first step of the surgical process, the patient is disposed on a surgical table in either the supine position (i.e., lying face up with the anterior aspect of the pelvis disposed directly upward) or the lateral decubitus position (i.e., with the hip joint to be repaired facing directly upward). The patient is then firmly retained in place using a hip positioning device that is fixedly secured to the surgical table. One type of hip positioning device which is well known in the art to position the patient in the lateral decubitus position includes a pair of opposing support members that firmly bear against the anterior and posterior aspect of the pelvis. Together, the support members serve to hold the pelvis stable during the hip replacement procedure.

Upon incising the patient, the ligaments and muscle in the hip joint region are separated to permit access to the hip joint. The native femoral head is then severed from the remainder of the femur by cutting through the femoral neck using an appropriate surgical instrument, such as a saw.

With the native femoral head removed therefrom, the acetabulum is then reconstructed. Specifically, the hip socket is first reamed to remove articular cartilage and shape the pelvic bone in its desired configuration (i.e., as a smoothed, hemispherical, cup-like socket). After completion of the reaming process, a prosthetic, cup-like, acetabular component (also referred to in the art simply as an acetabular cup) is removably mounted onto the proximal end of an elonaged, rod-shaped implantation instrument that is commonly referred to in the art as an inserter. Holding the distal end of the inserter, the acetabular component is aligned within the reamed portion of the pelvis.

The acetabular component is often fittingly retained in place, or impacted, within the reamed acetabulum by forcefully striking the distal end of the implantation with a mallet or other similar instrument. Various means are used to additionally secure the acetabular component within the hip socket and include, inter alia, (i) applying an adhesive between the acetabular component and the pelvic bone, (ii) driving fastening elements (e.g., screws) through the acetabular component and into the pelvic bone and (iii) roughening the exterior surface of the acetabular component to promote frictional engagement with the pelvic bone.

Once implantation of the acetabular component is completed, the proximal end of the femur is hollowed out so as to define a canal that is dimensioned to fittingly receive the elongated metal stem for the femoral component, the stem being preferably retained therein using any combination of adhesives, fastening elements and/or frictional engagement. With the stem of the femoral component retained within the femur, the prosthetic femoral head (typically constructed as a metal ball) is secured onto the free end of the stem. Once implantation of the femoral and acetabular prosthetics has been completed, the artificial femoral head is disposed within the artificial acetabulum, thereby completing reconstruction of the acetabulofemoral joint.

The success rate associated with total hip replacement surgery has been found to be largely dependent upon a number of relevant factors. In particular, it has been found that proper orientation of the implanted acetabular component within the reamed pelvic region is critical to the overall success of the surgery. Improper orientation of the acetabular component can lead to, among other things, component impingement as well as dislocation of the hip joint, which is highly undesirable. Accordingly, it is to be understood that implanting the acetabular component in the proper orientation relative to the pelvis is of paramount importance.

Traditionally, proper orientation of the acetabular component is accomplished by the surgeon by identifying certain anatomical landmarks on the pelvis and, in turn, visually estimating the proper angle of orientation relative thereto. Referring now to FIG. **1**, there is shown a front perspective view of a normal human pelvis **11** that is oriented such that the right acetabulum **12** is readily identifiable. As can be seen, pelvis **11** includes three imaginary orthogonal reference planes that are defined using specified anatomical landmarks. Specifically, the left anterior superior iliac spine (ASIS) **13**, the right anterior superior iliac spine **15** and the pubic symphysis **17** together define the anterior pelvic plane **19**. The anterior pelvic plane **19** extends vertically when the patient is standing upright and runs generally in parallel with the coronal plane of the body (i.e., the vertical plane that separates the body into ventral and dorsal sections). The transverse plane **21** extends horizontally when the patient is standing upright and extends from the left side of pelvis **11** to the right side of pelvis **11**. The sagittal plane **23** extends vertically when the patient is standing upright and extends from the front, or anterior, of pelvis **11** to the back, or posterior, of pelvis **11**.

Acetabular components are typically constructed from one or more pieces that together create a generally hemispherical cup. As such, it is to be understood that an acetabular component is shaped to define an imaginary center axis that extends through its apex. It is the relationship between the center axis for the acetabular component and the orthogonal planes of pelvis **11** that is used to properly orient the acetabular cup during total hip replacement.

There are two primary angles that are used to properly orient an acetabular component within reamed acetabulum **12**, namely, (i) abduction and (ii) anteversion. Abduction of the acetabular component is the angle between transverse plane **21** and the main axis for the acetabular cup as projected

onto anterior pelvic plane **19**. Anteversion of the acetabular component is the angle between anterior pelvic plane **19** and the main axis for the acetabular cup as projected onto transverse plane **21**. Traditionally, the ideal orientation of an acetabular cup within reamed acetabulum **12** is defined as approximately 40-50 degrees of abduction and approximately 15-25 degrees of anteversion.

Visual estimation of the abduction and anteversion angles has been found to be very difficult to assess during total hip replacement since the aforementioned pelvic reference planes are imaginary in nature. In addition, it should be noted that the pelvis is encased in soft tissue and is typically covered with surgical drapes during the procedure, thereby rendering visualization of the pelvic reference planes nearly impossible to achieve. Furthermore, even if the orientation of the pelvis is accurately determined, the ability of the surgeon to visually estimate instrument angles relative thereto is highly subjective and therefore prone to error.

In view of the aforementioned shortcomings associated with using visual estimation means for determining proper orientation of the acetabular cup, mechanical alignment guides have been recently developed for use in connection with hip replacement surgeries. Mechanical alignment guides provide the surgeon with a visual reference of the orientation of the acetabular component relative to the plane of the patient and operating room table. Although well known and widely used in the art, mechanical alignment guides of the type as described above have been found to have the potential to introduce significant error. In particular, the use of mechanical alignment guides requires that the pelvis be positioned properly prior to draping the patient for surgery, which is not always achieved. In addition, mechanical alignment guides fail to account for any intraoperative changes in pelvic orientation.

Accordingly, electronic surgical guidance systems are well known in the art and are used to assist in properly orienting prosthetic components, such as acetabular components, within a patient. Electronic surgical guidance systems allow for a target, or ideal, orientation angle for the acetabular component to be input into a central controller. Using spatial orientation data derived from sensors mounted on the implantation instrument, the controller provides feedback signals to the surgeon that indicate when the acetabular component is disposed at the desired angle of orientation.

For example, in U.S. Patent Application Publication No. 2010/0249796 to J. H. Nycz, which is incorporated herein by reference, there is disclosed a surgical instrument for implanting a prosthetic member. The instrument includes an orientation sensor that detects an initial orientation of the prosthetic member and an implanting orientation of the prosthetic member. The instrument further includes a memory module and an input device that receives a user input to transfer the initial orientation detected by the orientation sensor into the memory module for storage. Furthermore, the instrument includes an orientation feedback device that selectively provides an orientation feedback signal to the user. Moreover, the instrument includes a controller that causes the orientation feedback device to provide the orientation feedback signal when the implanting orientation detected by the orientation sensor is substantially equal to the initial orientation stored in the memory module.

Although well known in the art, surgical guidance systems of the type described above have been found to suffer from a few notable shortcomings.

As a first shortcoming, surgical guidance systems of the type described above are rather complex in their construction and use. As a result, it has been found that the costs associated with such systems are largely prohibitive. In addition, the technical expertise that is required to operate such a system is rather significant and lacks user-intuitiveness and thereby necessitates that the surgeon overcome a considerable learning curve prior to first use, which is highly undesirable.

As a second shortcoming, surgical guidance systems of the type as described above typically require that a reference point, or marker, be electronically identified in the pelvis as part of lengthy preparatory step. Once the reference marker in the pelvis is electronically established, orientation of the instrument is then standardized, or calibrated, relative to the reference marker. As can be appreciated, the aforementioned multi-stepped calibration process has been found to be both time-consuming and labor-intensive in nature, which is highly undesirable.

BRIEF SUMMARY OF THE INVENTION

It is an object of the present invention to provide a new and improved system for properly orienting orthopedic implants within a patient.

It is another object of the present invention to provide a system of the type as described above that provides a surgeon with electronic guidance in properly orienting an acetabular component within the pelvis during implantation.

It is yet another object of the present invention to provide a system of the type as described above into which can be input a target, or ideal, range of orientation of an acetabular component relative to at least one pelvic reference plane.

It is still another object of the present invention to provide a system of the type as described above that provides a feedback signal when the acetabular component falls within the target range of orientation.

It is yet still another object of the present invention to provide a system of the type as described above that does not require standardization, or calibration to a particular orientation, prior to each surgery.

It is another object of the present invention to provide a system of the type as described above that has a limited number of parts, is inexpensive to manufacture and is easy to use.

Accordingly, as a principal feature of the present invention, there is provided surgical guidance system for use in properly orienting a surgical instrument relative to at least one anatomical reference point on a patient, the patient being retained by a support device that contacts the patient at a particular location relative to the at least one anatomical reference point, the system comprising: (a) a reference sensor adapted to be fixedly coupled to the support device, the reference sensor collecting a first set of spatial orientation data, (b) a tool sensor adapted to be coupled to the surgical instrument, the tool sensor collecting a second set of spatial orientation data, and (c) a processor in electronic communication with the reference sensor and the tool sensor, the processor collecting the first and second sets of spatial orientation data, wherein the processor calculates the actual orientation of the surgical instrument relative to the at least one anatomical reference point using the first and second sets of spatial orientation data.

As another feature of the present invention, there is provided method for orienting a surgical instrument relative to at least one anatomical reference point on a patient, the method comprising the steps of (a) providing a support device, the support device contacting the patient at a particular location relative to the at least one anatomical reference point, (b) securing a reference sensor to the support device, the reference sensor collecting a first set of spatial orientation data, (c) mounting a tool sensor onto the surgical instrument, the tool

sensor collecting a second set of spatial orientation data, and (d) calculating the actual orientation of the surgical instrument relative to the at least one anatomical reference point using the first and second sets of spatial orientation data.

Various other features and advantages will appear from the description to follow. In the description, reference is made to the accompanying drawings which form a part thereof, and in which is shown by way of illustration, an embodiment for practicing the invention. The embodiment will be described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the invention. The following detailed description is therefore, not to be taken in a limiting sense, and the scope of the present invention is best defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings wherein like reference numerals represent like parts:

FIG. **1** is a front perspective view of a normal human pelvis, the pelvis being shown with the anterior pelvic, transverse and sagittal reference planes defined in relation thereto;

FIG. **2** is a front perspective view of a surgical guidance system constructed according to the teachings of the present invention, the surgical guidance system being shown with a normal human pelvis positioned in the lateral decubitus position therewithin for ease in understanding its use;

FIG. **3** is a front perspective view of the anterior component of the support device shown in FIG. **1**, the support device being shown with the reference sensor fixedly mounted thereon;

FIG. **4** is a front perspective view of the surgical instrument shown in FIG. **2**, the surgical instrument being shown with the tool sensor exploded therefrom, the tool sensor being broken away in part to view its internal circuitry; and

FIGS. **5**(*a*) and **5**(*b*) are sample screen displays provided on the monitor shown in FIG. **2**, the sample screen displays being shown at separate stages during the process of orienting the acetabular component within the pelvis.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, there is shown a surgical guidance system constructed according to the teachings of the present invention, the surgical guidance system being identified generally by reference numeral **111**. In use, surgical guidance system **111** facilitates proper orientation of a surgical instrument relative to at least one anatomical reference point on a patient, as will be described in detail below.

For simplicity purposes only, surgical guidance system **111** is described herein for use in connection with a full hip replacement procedure. More specifically, system **111** is described in detail herein as being used to facilitate proper orientation of an acetabular component within a pelvis during an implantation process. However, it is to be understood that system **111** is not limited to use assisting in the proper orientation of orthopedic implants, such as acetabular components. Rather, it is envisioned that system **111** could be used in connection with any surgical procedure that requires real-time guidance in maintaining a surgical instrument within a particular range of spatial orientation relative to at least one anatomical reference point on a patient.

As seen most clearly in FIG. **2**, surgical guidance system **111** comprises a surgical table **113** adapted to support a patient, a support device **115** fixedly coupled to table **113** for retaining pelvis **11** in a desired position, a surgical instrument **117** for use in implanting a prosthetic component in pelvis **11**, a reference sensor **119-1** fixedly coupled to support device **115** for collecting spatial orientation data that can be used to locate at least one anatomical reference point on pelvis **11**, a tool sensor **119-2** coupled to instrument **117** for collecting spatial orientation data that can be used to identify the orientation of instrument **117**, a processor **121** electrically coupled to sensors **119** for calculating, in real-time, the spatial orientation of instrument **117** relative to the at least one anatomical reference point on pelvis **11**, and an indicator **123** in electrical communication with processor **121** for providing a feedback signal that relates to the actual orientation of instrument **117** relative to the at least one anatomical reference point on pelvis **11**. For purposes of simplicity, only the pelvis **11** of a patient is shown on table **113** in the present example.

As noted above, support device **115** is fixedly mounted onto table **113** and serves, inter alia, to retain pelvis **11** in the desired lateral decubitus position. Support device **115** is represented herein as comprising an anterior component **125** and a posterior component **127** that are independently secured to table **113**. Together, components **125** and **127** apply opposing forces on pelvis **11** and thereby serve as a brace for stabilizing pelvis in a fixed position.

Although support device **115** is represented herein as comprising two separate anterior and posterior components **125** and **127**, it is to be understood that support device **115** could be alternatively constructed as a unitary, generally U-shaped component without departing from the spirit of the present invention.

As seen most clearly in FIGS. **2** and **3**, anterior component **125** comprises a vertical support beam **129**, a generally T-shaped frame **131** pivotally coupled to support beam **129**, upper and lower arms **133-1** and **133-2** slidably coupled to frame **131** and a plurality of stability members **135** for locating and applying pressure onto selected bony landmarks on pelvis **11**, as will be described further in detail below.

Support beam **129** is an elongated, rigid member that is fixedly secured to table **113** by a clamp **137** or other similar coupling mechanism. As can be seen, support beam **129** is preferably coupled to table **113** in such a manner so as to extend in a generally vertical orientation. An elongated stem **139** is fixedly secured to beam **129** and extends outwardly therefrom in the direction towards posterior component **127**. An enlarged ball **141** is formed onto the free end of stem **137** and assists in the pivotal coupling of frame **131** to support beam **129**, as will be described further below.

As seen most clearly in FIG. **3**, T-shaped frame **131** is a rigid, unitary member that includes a vertical portion **131-1** that is generally U-shaped in transverse cross-section and a horizontal portion **131-2** that extends in a generally orthogonal relationship relative to vertical portion **131-1**. A shortened stem **143** extends orthogonally out from the anterior side of frame **131** and is secured thereto by a bracket **145**. An enlarged ball **147** is formed on the free end of shortened stem **143** and is coupled to ball **141** by a clamp **149** that is generally C-shaped in transverse cross-section.

As can be appreciated, clamp **149** is designed to be tightened in order to securely retain balls **141** and **147** therewithin. Due to its rounded construction, each of balls **141** and **147** is capable of rotation within clamp **149**. In this capacity, ball **141**, ball **147** and clamp **149** together create a pivotal coupling mechanism that enables frame **131** to pivot freely in all directions relative to beam **129**, which is useful to account for any pelvic obliquity.

Upper and lower arms **133-1** and **133-2** are independently slidably coupled to vertical portion **131-1** at opposite ends

thereof. Specifically, upper arm **133-1** is secured to frame **131** by a first stability member, or outrigger, **135-1** that extends longitudinally through arm **133-1** and, in turn, transversely through a vertical slot **151-1** formed in the upper region of vertical portion **131-1**. Similarly, lower arm **133-2** is secured to frame **131** by a second stability member, or outrigger, **135-2** that extends longitudinally through arm **133-2** and, in turn, transversely through a vertical slot **151-2** formed in the lower region of vertical portion **131-1**. Although outriggers **135-1** and **135-2** are represented herein as unitary members that extend through the entirety of arms **133-1** and **133-2**, respectively, it is to be understood that each of outriggers **135-1** and **135-2** could be alternatively constructed as a plurality of separate pieces (e.g., with a first piece extending outward from one end of each arm **133** and a second section extending out from the opposite end of each arm **133**) without departing from the spirit of the present invention.

In addition, it should be noted that a third stability member **135-3** is provided that extends transversely through a lateral slot **151-3** formed in horizontal portion **131-2**. As will be described further in detail below, stability members **135** are designed to align and bear directly against corresponding anatomical landmarks on pelvis **11** and thereby assist in defining pelvic reference planes.

Each stability member **135** preferably includes an elongated, externally threaded rod **153** that is dimensioned to fittingly protrude through its associated slot **151**. An enlarged abutment, or stability, pad **155** is fixedly mounted onto one end of each threaded rod **153**. In the present embodiment, each pad **155** has a sufficiently cushioned, disc-shaped construction. However, it is to be understood that pads **155** could be alternatively constructed without departing from the spirit of the present invention. For example, pads **153-1** and **153-2**, which in the present example bear against left ASIS **13** and right ASIS **15**, respectively, could be alternatively provided with a curved profile to conform against the lateral aspect of each ASIS in order to provide additional stability to the pelvis.

In use, pads **155** are designed to bear directly against anatomical landmarks on pelvis **11** that are, in turn, used to define anterior pelvic plane **19**. Specifically, in the present example, pad **155-1** is disposed in direct contact against the against left ASIS **13**, pad **155-2** is disposed in direct contact against right ASIS **15** and pad **155-3** is disposed in direct contact against pubic symphysis **17**. As such, the abutment surface, or free end, of pads **155** together define anterior pelvic plane **19**.

It should be noted that threaded rods **153-1** thru **153-3** are preferably equal in length. As a result, pads **155-1** thru **155-3** extend in front of frame **131** a generally fixed (i.e. equal) distance. Therefore, it is to be understood that the plane defined by T-shaped frame **133** lies in parallel with the anterior pelvic plane **19** defined by pads **155** (and, as a consequence, generally orthogonal to transverse plane **21** and sagittal plane **23**).

Due to the inclusion of linear slots **151**, each threaded rod **153** is designed to travel therewithin in order to accommodate variances in the location of anatomical reference points for different size patients. It should be noted that each pad **155** is limited to linear displacement within the defined reference plane (i.e., anterior pelvic plane **19**). In other words, pads **155-1** and **155-2** can be vertically adjusted (i.e., along the medial-lateral path) and pad **155-3** can be horizontally adjusted (i.e., along the proximal-distal path). In addition, it should be noted that pad **155-3** can be axially displaced along rod **153** in a limited fashion (i.e., along the anterior-posterior path) to account for slight variances in the amount of soft tissue covering the bony landmark that pad **155-3** is designated to locate.

An enlarged knob **157** is threadingly mounted onto the free end of each rod **153** and is designed to selectively engage frame **131** to fix the position of each stability member **135** in relation to frame **131**.

As seen most clearly in FIG. **3**, reference sensor **119-1** is fixedly mounted onto vertical portion **131-1** of frame **131** in a co-planar relationship relative thereto. As will be described further in detail below, reference sensor **119-1** is designed to collect spatial orientation data and, in turn, electrically transmit the data to processor **121**. Because the main longitudinal axis LA_1 of reference sensor **119-1** lies in parallel with the abutment surfaces of pads **155** and, as a consequence, anterior pelvic plane **19**, the spatial orientation data collected by reference sensor **119-1** can be readily used to calculate spatial orientation information for each of the various reference planes for pelvis **11**.

Although reference sensor **119-1** is shown herein as mounted directly on frame **131**, it should be noted that sensor **119-1** could be alternatively mounted onto other fixed objects in the immediate environment (e.g., beam **129** or table **113**) as long as the orientation of the main longitudinal axis LA_1 for sensor **119-1** is known relative to anterior pelvic plane **19**. If reference sensor **119-1** is alternatively mounted onto beam **129** or table **113**, it is to be understood that frame **131** is preferably held fixed in relation to beam **129** (i.e., no longer pivotally displaceable) and therefore would no longer be able to account for any obliquity of the pelvis.

Referring now to FIGS. **2** and **4**, surgical instrument **117** is represented herein as being in the form of a shell inserter **161** on which is removably mounted an acetabular component **163**. As will be described further in detail below, inserter **161** can be used to insert acetabular component **163** in place within a reamed acetabulum in pelvis **11**. However, it should be noted that surgical instrument **117** is not limited to tools used to insert acetabular components **163** into the pelvis. Rather, it is to be understood that surgical instrument **117** represents any surgical instrument that would ideally require spatial orientation guidance relative to at least one anatomical reference point on a patient.

Inserter **161** is an elonaged implantation instrument that includes an elongated cylindrical rod **165** on which is coaxially mounted an enlarged handle **167**. Together, rod **165** and handle **167** share a common longitudinal axis LA_2.

Acetabular component **163** is represented herein as a dome or hemispherically-shaped cup that includes an interior surface **163-1** and an exterior surface **163-2**. An internally threaded bore (not shown) is preferably formed into interior surface **163-1** at its approximate center and is dimensioned to receive a complementary threaded element (not shown) formed onto the free end of cylindrical rod **165**. In this capacity, it is to be understood that acetabular component **163** can be removably screwed onto inserter **161** in coaxial alignment therewith.

As will be described further below, acetabular component **163** is preferably disposed into proper position within the reamed acetabulum by holding and manipulating handle **167**. With acetabular component **163** properly oriented within the reamed acetabulum, the distal end of inserter **161** can be struck with a mallet or other similar instrument to forceably wedge component **163** into place within pelvis **11**, outer surface **163-2** being preferably roughened to increase the retentive strength of the impaction.

Tool sensor **119-2** is removably mounted onto handle **167** and is designed to collect spatial orientation data relating to

the position of instrument **117**, the data being electrically transmitted to processor **121**. As seen most clearly in FIG. **4**, each sensor **119** preferably includes an outer protective casing **169** that is shaped to define an enclosed interior cavity **171**. Casing **169** is generally rectangular in configuration and defines a main longitudinal axis.

A sensor module **173** is disposed within interior cavity **171** and is designed to collect spatial orientation data in relation to its main longitudinal axis (or other similar reference axis). Preferably, sensor module **173** includes both a solid-state, 3-axis accelerometer as well as a 3-axis magnetometer. For example, sensor module **173** may be of the type manufactured and sold by STMicroelectronics of Lexington, Mass. under model number LSM303DLM. However, it is to be understood that sensor module **173** could be provide with additional or alternative spatial orientation detection means, such as a gyroscope, without departing from the spirit of the present invention.

As can be appreciated, the accelerometer and magnetometer for sensor module **173** serve to define coordinate systems that are aligned in relation to the main sensor longitudinal axis (or other similar reference axis). Specifically, the accelerometer measures the direction and magnitude of gravity relative to the reference axis. Similarly, the magnetometer measures the direction and magnitude of the immediate magnetic field relative to the reference axis. Since gravitational and magnetic fields are fixed in space, sensor module **173** can thereby be used to derive spatial orientation data relative to its main reference axis, as will be described further below.

As noted briefly above, reference sensor **119-1** is preferably mounted onto vertical portion **131-1** of frame **131** such that its main longitudinal axis LA_1 lies substantially in parallel with pads **155** and, as a consequence, anterior pelvic plane **19**. As a result, spatial orientation data collected by reference sensor **119-1** can be readily used by processor **121** to identify the location of each of the various reference planes for pelvis **11** without the need for preliminarily locating and marking anatomical reference points (as well as calibrating instrument sensor **119-2** relative thereto), which is a principal object of the present invention.

Similarly, tool sensor **119-2** is mounted onto handle **167** such that its main longitudinal axis LA_3 lies substantially in parallel with the main longitudinal axis LA_2 for inserter **161**. In this capacity, spatial orientation data collected by reference sensor **119-2** can be used to determine the real-time spatial orientation of instrument **117**. Accordingly, processor **121** can utilize the spatial orientation data for instrument **117** (derived from tool sensor **119-2**) and the spatial orientation data for the anatomical reference planes (derived from reference sensor **119-1**) to guide surgical instrument **117** in the proper orientation relative to pelvis **11**, as will be explained further below.

It should be noted that casing **169** for tool sensor **119-1** is preferably provided with a longitudinal recess **175** along its bottom surface that is dimensioned to fittingly receive handle **167**. As can be appreciated, the fitted mating relationship between tool sensor **119-1** and handle **167** assures parallel alignment of the longitudinal axis LA_3 for sensor **119-1** with the longitudinal axis LA_2 of inserter **161**, which is highly desirable.

It should also be noted that tool sensor **119-1** is preferably removably mounted onto inserter **161**. For example, tool sensor **119-1** may be releasably retained onto handle **167** using straps (or other similar fastening elements) or simply by disposing sensor **119-1** on inserter **161** and manually gripping both elements together. As can be appreciated, the removable mounting of tool sensor **119-1** onto instrument **117** introduces a number of notable advantages including, but not limited to, (i) enabling use of sensor **119-1** on a wide variety of different surgical instruments without the need for preliminary calibration and (ii) permitting proper sterilization of inserter **161** without jeopardizing the electrical integrity of sensor module **173** (with sensor **119-1** being preferably retained within a sterile plastic bag or other similar sterile container during its use).

As noted briefly above, a processor, or central controller, **121** is electrically coupled to sensors **119-1** and **119-2** by wires **177-1** and **177-2**, respectively (wires **177** being represented herein, in part, in simplified lined form for ease of illustration). It should be noted that processor **121** need not be connected to sensors **119** by wires **177**. Rather, it is to be understood that processor **121** could be electrically coupled to sensors **119** by alternative means (e.g., through wireless communication) without departing from the spirit of the present invention.

In the present example, processor **121** is represented as a stand-alone component that is preferably integrated into a conventional compute device, such as a personal computer. However, it should be noted that processor **121** need not be separate from either sensors **119** or indicator **123**. Rather, it is to be understood that processor **121** could be directly integrated into sensor **119-1**, sensor **119-2** or indicator **123** without departing from the spirit of the present invention.

As referenced above, each sensor **119** measures the position and magnitude of both gravitational and magnetic field vectors relative to its corresponding reference axis. The measured vector data is then transmitted to processor **121** for analysis. Using a mathematical algorithm programmed thereon, processor **121** is able to calculate the spatial orientation of surgical instrument **117** relative to anterior pelvic plane **19**. It is also to be understood that, in the present example, processor **121** can be additionally programmed to calculate the abduction angle and the anteversion angle of acetabular component **163** relative to pelvis **11**, which is a principal object of the present invention.

It is important to note that rotation of inserter **117** about its longitudinal axis LA_2 cannot be reliably controlled by a surgeon during the implantation process. Likewise, the longitudinal location of tool sensor **119-2** along the length of handle **167** cannot be easily maintained. Accordingly, as a principal feature of the present invention, it should be noted that the mathematical algorithm programmed on processor **121** that is used to calculate abduction and anteversion is not affected by any variance in axial rotation or longitudinal displacement of tool sensor **119-2**, which is highly desirable.

Specifically, spatial orientation data collected from tool sensor **119-2** can be analyzed in view of the anatomical reference planes defined by pelvis **11** (that are, in turn, calculated using spatial orientation data from reference sensor **119-1**). The relative orientation between tool sensor **119-2** and the pelvic reference planes can be broken down into roll (rotation about the X axis), pitch (rotation about the Y axis) and yaw (rotation about the Z axis). As can be appreciated, rotation of inserter **117** about its longitudinal axis LA_2 is equivalent to yaw. Accordingly, since rotation of inserter about its longitudinal axis LA_2 is not reliably controlled by the user, the orientation of tool sensor **119-2** is preferably corrected by the algorithm to filter out any rotation about the Z axis. The result is a tool sensor **119-2** that can be used to determine roll and pitch relative to pelvis **11**, with roll and pitch being synonymous in this case for anteversion and abduction, respectively.

Processor **121** is preferably disposed in electrical communication with an indicator **123** that is adapted to provide a real-time visual feedback signal relating to the orientation of

instrument **117** relative to defined anatomical reference planes for pelvis **11**. In the present example, indicator **123** is represented as a monitor that is disposed in close proximity to the surgeon to allow for greater ease in viewing during the surgical procedure.

It should be noted that indicator **123** is not limited to a monitor to provide a visual feedback signal. Rather, it is to be understood that indicator **123** could be in the form of alternative visual indicators, such as one or an array of light emitting diodes, without departing from the spirit of the present invention.

It should also be noted that indicator **123** need not be separate from the remainder of system **111**. Rather, it is to be understood that indicator **123** could be directly integrated into any of the other components of system **111**, such as instrument **117**, without departing from the spirit of the present invention.

It should further be noted that indicator **123** is not limited to providing a feedback signal that is visual in nature. Rather, it is to be understood that indicator **123** could be provided with additional or alternative sensory feedback means (e.g., an auditory alarm) without departing from the spirit of the present invention.

As will be described further below, a target, or ideal, range of orientation for surgical instrument **117** relative to one or more defined anatomical reference planes can be input into processor **121** to provide surgical guidance during a procedure. In this manner, processor **121** can provide a feedback signal on indicator **123** when instrument **117** falls either inside or outside of the target range.

Specifically, referring now to FIG. **5**(*a*), there is shown a sample screen display **210** of a graphical user interface that is provided on indicator **123** when system **111** is used to implant an acetabular component **163** in pelvis **11**, the graphical user interface being identified generally by reference numeral **211**. As can be seen, system **111** is designed so that the user is able to input into processor **121** the hip to be replaced (i.e., left or right), the desired, or target, angle of anteversion, the desired, or target, angle of abduction as well as the degree of allowable error, each of said modifiable factors being represented in corresponding user intuitive windows **213-1** thru **213-4**, respectively, on graphical interface **211**. In the present example, the right hip is set to be replaced, the target angle of anteversion is set at 25 degrees, the target angle of abduction is set at 45 degrees and the amount of allowable error is set at 3 degrees.

Graphical user interface **211** is also designed to include a Cartesian coordinate system, or X-Y, graph **215** that represents the actual angle of anteversion for acetabular component **163** (represented herein as the X axis of the graph) relative to the actual angle of abduction for acetabular component **163** (represented herein as the Y axis of the graph). A dot-shaped cursor **217** is provided on graph **215** that depicts, in real-time, the actual anteversion and abduction angles for acetabular component **163** using the spatial orientation data compiled from sensors **119** and, in turn, processing the data using the mathematical algorithm programmed on processor **121**. Accordingly, it is to be understood that as the anteversion and abduction angles for acetabular component **163** vary, the position of cursor **217** moves, or floats, in accordance therewith.

In addition, a ring **219** is provided on graph **215** that depicts the target range of acceptable acetabular orientation. As can be appreciated, the center of ring **219** is defined using the desired angles of anteversion and abduction that are input into processor **121** and, in turn, displayed in windows **213-2** and **213-3**, respectively. The diameter of ring **219** is represented as twice the value of the allowable error that is displayed in window **213-4**.

Accordingly, it is to be understood that a surgeon can use system **111** in the following manner to ensure proper orientation of an acetabular component **163** in pelvis **11** during the implantation process. Specifically, the patient is positioned in the lateral decubitus position, with pads **155-1** thru **155-3** disposed in direct contact against left ASIS **13**, right ASIS **15** and pubic symphysis **17**, respectively. As a principal feature of the present invention, spatial orientation data collected from reference sensor **119-1** can be utilized to immediately ascertain the reference planes for pelvis **11** without the need for any (i) complex inspection of the orientation of pelvis **11** or (ii) any preparatory calibration of tool sensor **119-2** relative to one or more reference markings. Rather, once the patient is properly retained by support device **115**, system **111** is ready for use, which is highly desirable.

It should be noted that system **111** is not limited to use with the patient disposed in the lateral decubitus position. Rather, it is to be understood that **111** could be utilized with the patient disposed in alternative positions without departing from the spirit of the present invention. For example, system **111** could be implemented with the patient retained by support device **115** in the supine position (i.e., with the anterior aspect of pelvis **11** facing directly upward). As can be appreciated, when system **111** is utilized to perform hip replacement on a patient disposed in the supine position, pads **155** still bear against the anatomical landmarks on patient and therefore define the various pelvic reference planes. However, it should be noted that disposing the patient in the supine position requires that support device **115** be alternatively coupled to table **113** to enable each of pads **155** to bear against the upwardly facing anatomical landmarks. For instance, frame **131** could be held firmly in place against the anterior aspect of the patient using a strap that wraps around the posterior aspect of the patient. Otherwise, a horizontal beam could be attached to vertical beam **129**, thereby creating a unitary structure with an L-shaped configuration. Stem **139** would then protrude directly downward from the horizontal beam so that pads **155** are able to abut against the upward facing pelvic landmarks.

After the acetabulum has been properly prepared for implantation, the surgeon grasps handle **167** and manipulates inserter **161** so that acetabular component **163** aligns within the prepared acetabulum. With the target orientation information input into processor **121** (and displayed in windows **213**), the user relies upon graph **215** on graphical user interface **211** to properly orientate component **163**, with linear anteversion and abduction scales **220-1** and **220-2**, respectively, being provided along the periphery of graph **215** to facilitate in the guiding process.

As seen most clearly in the sample screen display **221** shown in FIG. **5**(*b*), once cursor **217** is positioned within ring **219**, a corresponding signal is sent from processor **121** to inform the surgeon that the proper orientation of component **163** has been achieved. In the present example, a pop-up tab **223** displaying the word "acceptable" is provided on graph **215** to provide positive feedback. However, it is to be understood that alternative signals (e.g., an auditory alarm or flashing illumination signal) could be used in place of tab **223** without departing from the spirit of the present invention.

With component **163** properly oriented, the surgeon then permanently secures component **163** to pelvis **11**. For example, the surgeon may impact component **163** within reamed acetabulum **12** by striking the distal end of inserter **161** with a mallet.

It should be noted that graphical user interface **211** could be provided with additional information to assist the surgeon during the implantation process. For example, in the present embodiment, a pelvic tilt meter **225** and a pelvic rotation meter **227** are provided on graphical user interface **211** to provide pelvic orientation information that is potentially useful to the surgeon.

It should also be noted that system **111** is not limited to providing a positive feedback signal (i.e., a signal when component **163** is properly oriented relative to pelvis **11**). Rather, system **111** could be alternatively or additionally designed to provide a negative feedback signal when undesirable conditions are detected, such as retroversion of acetabular component **163**.

As noted above, system **111** is not limited to use in guiding proper orientation of an acetabular component within the pelvis during implantation. Rather, it is envisioned that alternative surgical procedures could be similarly implemented using system **111** without departing from the spirit of the present invention. In particular, it is envisioned that system **111** could be used in connection with any surgical procedure that requires real-time guidance in maintaining a surgical instrument within a particular range of spatial orientation relative to at least one anatomical reference point.

For example, system **111** could be similarly used to prepare the acetabulum for the subsequent implantation of an acetabular component. As noted above, prior to implanting an acetabular component, articular cartilage and subchondral bone is removed from the acetabulum using a reaming instrument, or reamer. A traditional reamer includes an elongated longitudinal shaft on which is coaxially mounted a motor-driven, hemispherical reamer head. Accordingly, it is to be understood that by placing tool sensor **119-2** onto the longitudinal shaft of a reamer, system **111** can be used in a similar capacity to assist the surgeon in reaming the acetabulum in the proper orientation.

The embodiment shown in the present invention is intended to be merely exemplary and those skilled in the art shall be able to make numerous variations and modifications to it without departing from the spirit of the present invention. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

What is claimed is:

1. A surgical guidance system for use on a patient, the patient having at least one anatomical reference point, the surgical guidance system comprising:

(a) a support device adapted to contact the patient at a particular location relative to the at least one anatomical reference point;

(b) a reference sensor fixedly coupled to the support device for collecting a first set of spatial orientation data;

(c) a surgical instrument for use on the patient, the surgical instrument having a longitudinal axis;

(d) a tool sensor coupled to the surgical instrument for collecting a second set of spatial orientation data; and

(e) a processor in electronic communication with the reference sensor and the tool sensor, the processor collecting the first and second sets of spatial orientation data, wherein the processor calculates the actual orientation of the surgical instrument relative to the at least one anatomical reference point using the first and second sets of spatial orientation data.

2. The surgical guidance system as claimed in claim **1** wherein the support device comprises:

(a) a frame; and

(b) a plurality of stability members coupled to the frame, each stability member including an abutment pad that is aligned to directly bear upon a corresponding anatomical reference point on the patient.

3. The surgical guidance system as claimed in claim **2** wherein the support device further includes a vertical support beam to which the frame is pivotally coupled.

4. The surgical guidance system as claimed in claim **2** wherein the frame is a generally T-shaped member that includes a vertical portion and a horizontal portion, the vertical portion being shaped to define a pair of linear slots and the horizontal portion being shaped to define a single linear slot, each linear slot in the vertical and horizontal portions being adapted to slidably receive a corresponding stability member.

5. The surgical guidance system as claimed in claim **2** wherein the plurality of pads together defines an anatomical reference plane for the patient.

6. The surgical guidance system as claimed in claim **5** wherein each of the reference and tool sensors comprises:

(a) a casing shaped to define an interior cavity, the casing being shaped to define a reference axis; and

(b) a sensor module disposed with the interior cavity, the sensor module being adapted to collect spatial orientation data relative to the reference axis.

7. The surgical guidance system as claimed in claim **6** wherein the sensor module includes an accelerometer and a magnetometer.

8. The surgical guidance system as claimed in claim **6** wherein the reference axis for the reference sensor lies in parallel with the anatomical reference plane defined by the plurality of pads.

9. The surgical guidance system as claimed in claim **6** wherein the tool sensor is removably mounted onto the surgical instrument.

10. The surgical guidance system as claimed in claim **9** wherein the at least one reference axis for the tool sensor lies in parallel with the longitudinal axis for the surgical instrument.

11. The surgical guidance system as claimed in claim **1** wherein the processor is adapted to receive a target range of orientation of the surgical instrument relative to the at least one anatomical reference point.

12. The surgical guidance system as claimed in claim **11** wherein the target range of orientation of the surgical instrument is modifiable.

13. The surgical guidance system as claimed in claim **12** wherein the processing unit compares the actual orientation of the surgical instrument relative to the at least one anatomical reference point with the target range of orientation of the surgical instrument relative to the at least one anatomical reference point.

14. The surgical guidance system as claimed in claim **13** further comprising an indicator in electrical communication with the processing unit, the indicator identifying the actual orientation of the surgical instrument relative to the target range of orientation of the surgical instrument.

15. The surgical guidance system as claimed in claim **14** wherein the indicator provides a signal when the actual orientation of the surgical instrument relative to the at least one reference point falls within the target range of orientation for the surgical instrument relative to the at least one reference point.

16. The surgical guidance system as claimed in claim **15** wherein the signal provided by the indicator is visual.

17. The surgical guidance system as claimed in claim **14** wherein the indicator is in the form of a monitor that is

electrically connected to the processor, the monitor being adapted to display a graphical user interface that depicts the actual orientation of the surgical instrument relative to the target range of orientation for the surgical instrument.

18. A surgical guidance system for use in properly orienting a surgical instrument relative to at least one anatomical reference point on a patient, the patient being retained by a support device that contacts the patient at a particular location relative to the at least one anatomical reference point, the system comprising:

(a) a reference sensor adapted to be fixedly coupled to the support device, the reference sensor collecting a first set of spatial orientation data;

(b) a tool sensor adapted to be coupled to the surgical instrument, the tool sensor collecting a second set of spatial orientation data; and

(c) a processor in electronic communication with the reference sensor and the tool sensor, the processor collecting the first and second sets of spatial orientation data, wherein the processor calculates the actual orientation of the surgical instrument relative to the at least one anatomical reference point using the first and second sets of spatial orientation data.

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